

**UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s):	Schasteen <i>et al.</i>	Art Unit	1645
Serial No.:	10/799,083	Examiner:	Vanessa Ford
Filed:	March 12, 2004	Conf. No.	8520
For:	METHODS AND COMPOSITIONS FOR THE CONTROL OF COCCIDIOSIS		

**DECLARATION OF CHRISTOPHER D. KNIGHT AND JULIA J. DIBNER**

**UNDER 37 C.F.R. § 1.132**

Christopher D. Knight, Ph.D., and Julia J. Dibner, Ph.D., declare and state as follows:

1. I, Christopher D. Knight, have over twenty years of experience in the field of animal health and nutrition. Novus International Inc., a global leader in animal health and nutritional products, currently employs me as Vice-President for Research and Development. My employment by Novus International has been continuous for over seventeen years. Prior to my employment at Novus International Inc., I was employed by Monsanto in their Animal Sciences Division for over five years. My educational background includes a Bachelor of Science degree in Animal science awarded by Cornell University in 1975; a Master of Science degree in Monogastric Nutrition awarded by Purdue University in 1977; and a doctorate degree (*i.e.*, Ph.D.) in Monogastric Nutrition awarded by Purdue University in 1981. I have also published over approximately thirty journal articles or posters at internationally attended meetings, and I am an inventor on ten patents. Attached to this Declaration is a copy of my *curricula vitae*.
2. I, Julia J. Dibner, have over twenty years of experience in the field of animal health and biological sciences. Novus International Inc., a global leader in animal health and nutritional products, currently employs me as a Senior Scientist and Distinguished Fellow. My employment by Novus International has been continuous for over seventeen years. Prior to my employment at Novus International Inc., I was employed by Monsanto in their Animal Sciences Division for approximately ten years. My educational background includes a Bachelor of Arts degree in Biology and Anthropology awarded by the State University of New York at Binghamton; a Research Fellowship in Biochemistry at the State

University of New York at Binghamton; and a doctorate degree (*i.e.*, Ph.D.) in Cellular and Developmental Biology awarded by Washington University in St. Louis. I have also published over approximately ninety journal articles or posters at internationally attended meetings, and I am an inventor on seven patents. Attached to this Declaration is a copy of my curricula vitae.

3. We, Christopher D. Knight and Julia J. Dibner, identified as above, have reviewed and are familiar with U.S. Patent Application Publication No. 2004/0175391 (the '391 application; U.S. Serial No. 10/799,083) entitled "Methods and Compositions for the Control of Coccidiosis." The '391 application has claims directed toward methods for isolating viable oocysts with a hydrocyclone. The claimed oocyst/hydrocyclone technology is presently utilized by Novus International Inc. in the making of the ADVENT® Coccidiosis Control product, which is an orally applied coccidiosis live-vaccine that offers a number of advances within the field, including the elimination of hazardous chemicals in the vaccine.
4. Through our employment at Novus as indicated above, we both are familiar with and have supervised portions of the research and development efforts that resulted in the discovery of the methods currently claimed in the '391 application. At the outset of the project, we were skeptical that hydrocyclones could be used to isolate viable oocysts. To be useful for the production of a live-vaccine, the oocysts are required to be viable following isolation. Oocysts, however, were known in the art to be extremely fragile and destroyed by agitation, stirring, or even by the mechanical action of digestion. See, *e.g.*, newly identified supporting references showing the general state of the art, including U.S. Patent No. 4,808,404 ("The sporozoites of *Elimeria* species once out of their protective shells, *i.e.*, oocysts and sporocysts, are very fragile and lose their infectivity within a few days."); U.S. Patent No. 6,891,024 ("Oocysts and sporocysts are found in the intestinal contents but the fragile oocyst is commonly disrupted by the time feces are passed."); and U.S. Patent No. 6,998,126 ("The wall of the sporulated oocyst is ruptured by the mechanical action in the gizzard and intestinal tract . . ."). Our experience at Novus International in handling oocysts further confirms that they are extremely fragile and subject to rupture.
5. Thus, in the initial stages of the project resulting in the '391 application, we were skeptical that a hydrocyclone could be used to isolate a viable oocyst since hydrocyclones apply extreme sheer forces, which we thought were likely to destroy the oocysts. Hydrocyclones had not been previously used to isolate oocysts. At the time, our only knowledge of the use of hydrocyclones was for the removal of waste products, for example, in mining or other industrial applications. There were no positive indications

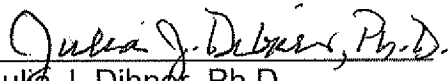
for using a hydrocyclone to separate oocysts, particularly when the oocysts needed to be viable.

6. In the recent Office Action concerning the '391 application, mailed on June 24, 2009, the Patent Office cites to a new reference referred to as Alesina *et al.* (SU 19984621763; "Alesina"). The abstract provided of Alesina refers to a hydrocyclone for use in microorganism suspension separation. The reference, however, makes no mention whether the microorganism suspension would be live or dead before or after separation. Furthermore, the term "microorganism" is not an art-recognized equivalent of oocysts, since oocysts are more akin to fertilized eggs, which are not yet developed enough to be infective. Physically, oocysts are also much larger and less dense than microorganisms such as bacteria, including structural differences in the outer membrane/cell wall that make oocysts substantially more fragile than bacteria. Consequently, oocysts would not be considered to be the same or substantially similar to the term "microorganisms" as set forth by the Patent Office.
7. The Office Action further states at page 7 that Conkle *et al.* "... suggest the use of other methods of processing oocysts to eliminate the use of harsh chemicals such as potassium dichromate." This is not technically correct, first, because Conkle still uses potassium dichromate as an oxidizing agent at page 8, line 6 of Conkle, such that potassium dichromate would still be present in their vaccine. Secondly, and more importantly, potassium dichromate is used for its biostatic/oxidizing ability (*i.e.*, to minimize bacterial growth within the remaining fecal matter), not for oocyst isolation. There is no relationship between potassium dichromate and new methods of separation/isolation. Thus, there is no relationship between potassium dichromate and the use or non-use of a hydrocyclone. Rather, as mentioned previously, there were a number of factors that made us initially believe that using a hydrocyclone would not be effective at isolating a viable oocyst for making a live-vaccine.
8. There were also additional obstacles that were overcome in arriving at the '391 application that may be worthy of consideration. Since the oocysts and the slurry particles from which the oocysts were isolated were of similar densities, it was difficult to find the appropriate pressure parameters that would allow effective isolation and not destroy the oocysts in the hydrocyclone. At the outset of the project, it appeared that any pressure that allowed separation of the oocyst from the slurry particles would also destroy the oocysts. The appropriate pressure conditions were ultimately discovered, however, and are fully described in the '391 application specification.

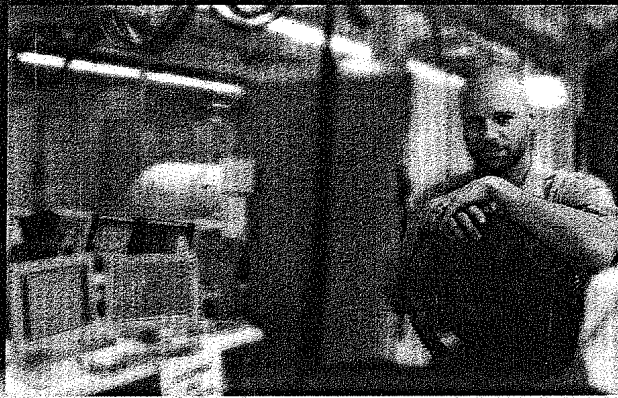
9. As a matter of general interest, we have also attached to this declaration a copy of an article from the St. Louis Business Journal, published in April of 2003. The Business Journal article identifies us, Christopher D. Knight and Julia J. Dibner, as St. Louis Technology Award recipients for our contributions in developing the ADVENT® vaccine, which is used to treat coccidiosis in poultry.
10. We further declare that all statements made herein are of our own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

  
Christopher D. Knight, Ph.D.

7/31/2007  
Date

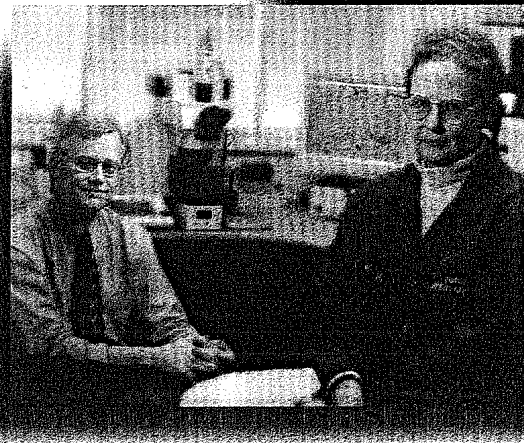
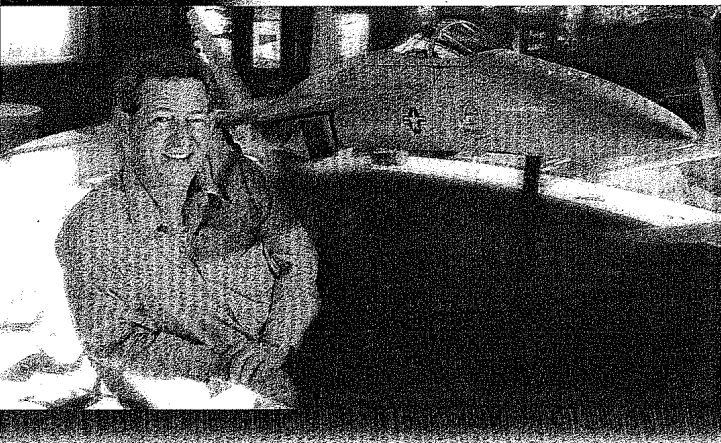
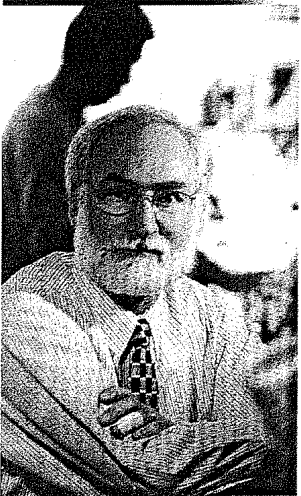
  
Julia J. Dibner, Ph.D.

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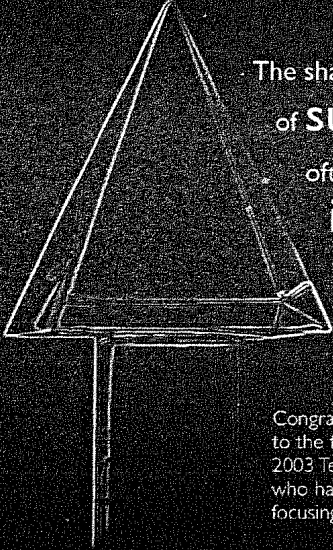


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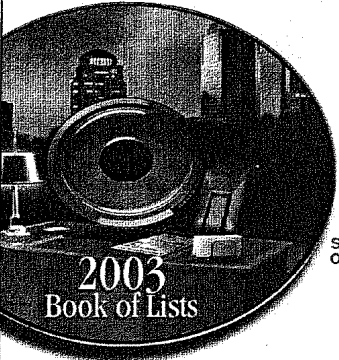
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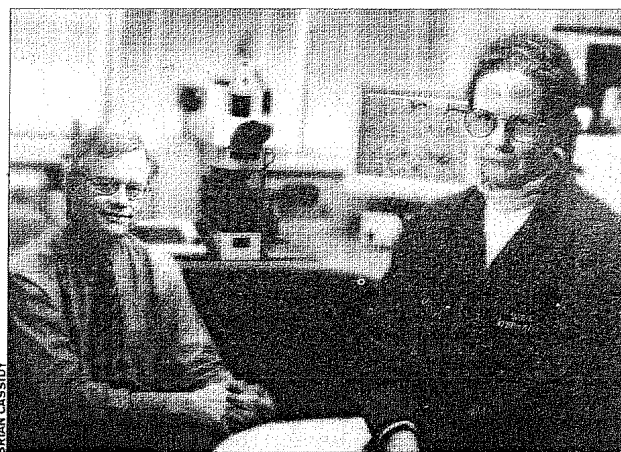
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## CHICKEN CURING

Scientists at Novus  
develop vaccine to treat  
No. 1 poultry threat

BY CHAD GARRISON  
[cgarrison@bizjournals.com](mailto:cgarrison@bizjournals.com)

Chicken producers the world over may soon be praising the names of Chris Knight and Julia Dibner, scientists with the animal agricultural firm Novus International Inc.

Last December, Knight, head of research and development for Novus, and Dibner, a senior scientist with the company, received USDA approval for Advent, a new vaccine they developed for the treatment of coccidiosis in broiler chickens. Coccidiosis, a potentially deadly parasitic protozoa, is estimated to cost the world's poultry producers some \$700 million in annual losses, according to industry publications.

In the United States, the highly contagious coccidiosis is the No. 1 threat for poultry producers, who spend between \$60 million and \$70 million annually on drugs designed to prevent chickens from catching the disease, according to the USDA.

Currently, some 90 percent of broiler chickens (those used primarily for food sources) are treated for coccidiosis through drugs and chemicals placed in their feed. Knight's and Dibner's vaccine, on the other hand, is sprayed onto young chicks a day after they are hatched. This biological treatment, in which the chicks are exposed to a non-threatening form of coccidiosis, causes the animals to develop natural antibodies that render them immune from the disease.

The two scientists, who have worked together for nearly 20 years (first at Mon-

Chris Knight and Julia Dibner have spent five years developing a coccidiosis vaccine.

santo and then Novus), spent the past five years working on the vaccine. Unlike the few other coccidiosis vaccinations for broiler chickens, Advent takes advantage of technology developed by Novus that allows scientist to accurately measure the number of living organisms within the vaccine: an important step in determining the vaccine's potency. Furthermore, the strict manufacturing process of the vaccine guarantees its purity.

Tim Cherry, a professor of poultry science at Stephen F. Austin State University in Nacogdoches, Texas, who has spent the past 13 years studying and researching coccidiosis, said the Advent vaccine is far more consumer- and producer-friendly than current methods of preventing the disease.

"There are two main concerns currently surrounding the traditional prevention methods of treating coccidiosis: resistance of the organism to drugs and the worldwide consumer preference for animals to be fed less drugs and chemicals," he said. "Advent addresses both of those issues because with the vaccine drug resistance is not a factor and you don't have to use drugs or chemicals in the feed."

Currently, Advent is being tested by nearly all the major poultry producers in the United States, and Knight and Dibner are confident its use will gain popularity once producers realize its efficiency and reliability.

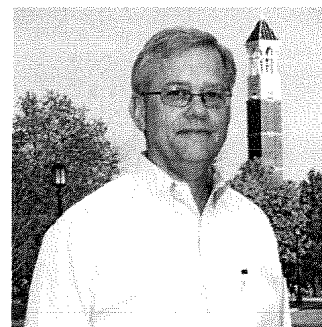
Of the 8.5 billion broiler chickens produced annually in the United States, only 7 percent to 8 percent of those birds are treated for coccidiosis through vaccinations, Knight said.

Novus International Inc., had sales of \$400 million last year. The company, headquartered in Maryville Center, with a research facility in St. Charles, was originally the Animal Feed Ingredients division of Monsanto Co. In 1991, the division was spun off from Monsanto and purchased by a Japanese joint venture.

## CURRICULUM VITAE

### Christopher D. Knight, Ph.D

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### Education

1977- 1981	Ph.D. in Monogastric Nutrition Purdue University, West. Lafayette, IN Department of Animal Science. Graduate Instructor, 1977-1981
1975- 1977	M.S. in Monogastric Nutrition Purdue University, West. Lafayette, IN Department of Animal Science. Graduate Research Assistant
1973- 1975	B.S. Animal Sciences Cornell University, Ithaca, NY
1971- 1973	A.A.S. Science Laboratory Technology State University of New York at Cobleskill

### Employment

2006- Present	Vice-President, Research & Development Novus International, Inc.
2001- 2006	Department Head, Research & Development Novus International, Inc.
1996- 2001	Director New Business Development Novus International, Inc.
1991- 1995	Manager and Director Nutrition Research Novus International, Inc.
1987- 1991	Research Group Leader Monsanto Company Animal Sciences Division Porcine Somatotropin Group
1981- 1986	Research Specialist and Research Group Leader Monsanto Co: Alimet Metabolism and Applications Research Group

## Key Accomplishments

- Developed and implemented a Novus International sponsored Graduate Scholarship program outside the U.S. to support graduate students in animal nutrition and health, and to develop a technical network of expertise that Novus can collaborate with in our basic and applied approach to product development and problem solving. This program allows us to encourage an international perspective to you graduates in animal agriculture as well as introduce the research based approach of Novus in world areas where Novus is expanding. This program began in 2006 in China and involves 8 different agriculture universities and provides 32 scholarships per year in addition to 8 internships to the US each year. Both Purdue University and University of Missouri-Columbia work collaboratively with Novus in the execution of certain aspects of this program. In 2008, we have expanded this program to include Pukyong National University, in Pusan Korea, specializing in Aquaculture and supporting 3 graduate students per year; and Bombay Veterinary College, Mumbai, India supporting one student per year in mineral metabolism. This program involves annual visits and joint university and industry seminars each year to facilitate industry and academic interaction and sharing of research. In each case, this program has been the first of its kind in each of these universities and offers a unique approach to industry and academic collaboration.
- Developed foundation data quantifying availability of ALIMET® Feed Supplement as a rumen-available and rumen by-pass methionine source in lactating dairy cattle and methods to predict methionine deficiency using existing nutritional models. These data resolved decades of research work to attempting to commercialize this product application that had failed due to unpredictable field results. The research demonstrated Alimet to be the most cost-effective source of post-ruminal methionine activity available, resulted in a US patent and the development of a \$5M/yr business for Novus. As of 2005, a new Ruminant Business Unit has been formed with 20 employees and agents and a portfolio of 8 products (including Alimet and MHA) for the dairy industry. Sales in FY08 were \$20M.
- Led the development and commercialization of OASIS® Hatchling Supplement, a hydrated nutritional supplement fed to young poultry in transit or to stimulate rapid onset of ad libitum feeding after placement. This patented product developed a new market in the poultry industry based on developmental research at Novus showing the impact of early nutrition on subsequent long term performance and health. Cumulative sales of this niche product have exceeded \$5M and resulted in the development of gastrointestinal health as a core research and development competency within Novus.
- Led the technology development, regulatory approval and early commercialization of ADVENT® Coccidiosis Control, an orally applied coccidiosis vaccine based upon technology that permits the in vitro determination of oocyst viability such that a vaccine of consistent potency can be produced and marketed. This represented a new area of



technology for Novus and in 2003, a jury of scientists and technology experts from Washington University and St. Louis University awarded the developers of this technology (Dr. Julia Dibner and Dr. Chris Knight) with The St. Louis Technology Award. The Advent Coccidiosis Control technology was among eight other winners from approximately 70 nominations in the St. Louis vicinity. In determining winners, the judges considered the scope, economic impact and overall significance of the new technology. Facilitated by the Academy of Science of St. Louis, the judging process also examined the level of sophistication of the entries and the innovation utilized to bring it to fruition. This technology represents a keystone of a business strategy that focuses on gastrointestinal health and drug-free poultry production.

- In 2007, successfully developed a low pathology strain of *E. tenella* that resulted in robust immunity with reduced lesion production in the bird and better subsequent production. This allowed for a re-introduction of Advent in the US market that has allowed for a significantly expanded market penetration of the vaccine and provided intellectual property to protect the selection process used to develop the strain.
- Established a new cost-efficient method of product development research, to insure Novus' capability to conduct scientifically and commercially relevant research across multiple species without requiring ownership or hands on care and management of research facilities. Initially divested Novus-owned animal research facilities and sought collaborative investment opportunities with scientific professionals in animal agriculture to provide capital for research facilities that would be controlled by the research partner but provide Novus with preferred status for conduct of research. To date we have formed 3 partnerships like this in the US that permits routine product development work in broilers, swine (weaning, grow-finish and lactating sows) and dairy cattle, all in commercial scale production environments. Similar agreements are under development in Brazil (commercial scale broiler research) and China (commercial scale swine research including wean, grow-finish and sow nutrition).
- The foundation product for Novus International is ALIMET® Feed Supplement, a source of methionine activity referred to as methionine hydroxyl analog or chemically DL-2-hydroxy-4-(methylthio) butanoic acid. Today this business represents approximately \$700M in annual revenue to Novus in a \$2B methionine market, however, in 1981 this represented about a \$20M business. In the course of my 25 year involvement with this product there has been a heated commercial controversy with respect the relative efficacy of Alimet and the competitive product DL-methionine (DLM). A close colleague (Dr. Julia Dibner) and I have had the responsibility of understanding the absorption, metabolism and utilization of Alimet, how it differs from that of DLM and the impact that the differences have on the commercial value of Alimet relative to DLM. Today based on a variety of independent and collaborative research efforts it is understood that the metabolism of Alimet is very different from DLM, that those differences result in differences in ad libitum feed intake (less than DLM at low supplementation rates, greater than DLM at the maximum response level) resulting in different dose responses for the two methionine sources. A substantial part

of the controversy was based on the a priori assumption that the two products must have the same dose response since they both provide methionine. With collaboration with various statistical experts, we have been able to establish that the two products in fact have different dose responses and have described the appropriate statistical methods for comparing two products that exhibit different dose responses (Poult. Sci. 85:947-954). The controversy will continue due to commercial conditions (Alimet is less expensive to manufacture than DLM) , however over the course of 25 years Alimet has continued to grow at a 25% compounded annual growth rate with over a 50% market share in the US. The science applied to this commercial issue has laid the technical foundation that has provided Novus with the technical credibility to expand our product offerings from amino acids into nutritional organic acid blends, organic trace minerals, ingredient preservation and coccidiosis control.

ALIMET® Feed Supplement, OASIS® Hatchling Supplement and ADVENT® Coccidiosis Control are registered trademarks of Novus International, Inc., St. Louis, MO.

## **Personal**

- Married 1982: Sandra J. Rogers (Purdue Food Science MS 1978).
- Children: Adam (22), Evan (19), Audrey (18)

## **Community Involvement**

- Subdivision Trustee: 1987-1989: Led resolution of road and storm sewer repair dispute
- St. Peter's Episcopal Church:
  - Youth Sponsor: 1984-1988
  - Sunday School Teacher: 1992-2006 (Variety of grades and curricula)
  - Vestry: 1989-1993
  - Founding Christian Education Commission & Chair: 1989-1993
  - Confirmation Teacher: 2005-6.
  - Founding and sustaining member of Haven of Grace: Home for unwed mothers
- Hobbies
  - Cooking
  - Gardening
  - Kid's Sports

## **Professional Societies & Honors**

- American Society of Animal Science
- Poultry Science Association
- 2003 St. Louis Technology Award for Advent Coccidiosis Control development
- 2007 Distinguished Alumni Award Purdue Department of Animal Science
- 2009 Distinguished Alumni Purdue School of Agriculture Award

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### Patents

1. U.S. 6,814,988 – Process for optimizing milk production.
- 2 U.S. 6,733,759 – Nutrient formulation and process for enhancing the health, livability, cumulative weight gain or feed efficiency in poultry and other animals.
- 3 U.S. 6,329,001 – Nutrient formulation and process for enhancing the health, livability, cumulative weight gain or feed efficiency in poultry and other animals.
- 4 U.S. 6,319,525 – Process for optimizing milk production.
- 5 U.S. 6,210,718 – Nutrient formulation and process for enhancing the health, livability, cumulative weight gain or feed efficiency in poultry and other animals.
- 6 U.S. 6,183,786 – Process for optimizing milk production.
- 7 U.S. 6,017,563 – Process for optimizing milk production.
- 8 U.S. 5,985,336 – Nutrient formulation and process for feeding young poultry and other animals.
- 9 U.S. 5,976,580 – Nutrient formulation and process for enhancing the health, livability, cumulative weight gain or feed efficiency in poultry and other animals.

10 U.S. 5,928,686 – Nutrient formulation and process for feeding young poultry and other animals.



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### **Education**

1976- 1980	Ph.D. in Cellular and Developmental Biology Washington University, St. Louis Division of Biology and Biomedical Sciences. Graduate Fellowship, 1976-1980
1972- 1975	Doctoral student in Biochemistry State University of New York at Binghamton Research Fellowship, 1974-1975 Graduate Assistant, 1972-1974
1969- 1972	B.A., Summa cum laude, June, 1972 State University of New York at Binghamton Majors in Biology and Anthropology

### **Employment**

2004-	Senior Scientist and Distinguished Fellow Cell Biology Research Novus International
2001- 2004	Senior Scientist and Senior Fellow Cell Biology Research Novus International
1996- 2001	Director and Senior Fellow Cell Biology Research Novus International
1991- 1995	Director and Fellow Cell Biology Research Novus International

1989- 1991	Science Fellow Monsanto Company Animal Sciences Division Alimet Metabolism Group Drug Delivery Discovery Group
1981- 1989	Research Specialist and Associate Fellow Monsanto Company Animal Sciences Division Alimet Metabolism Group Drug Delivery Discovery Group

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